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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/250,056	02/12/1999	JAMES D. MARKS	2307E-852	1647

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EXAMINER

HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 11/26/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/250,056

Applicant(s)

MARKS ET AL.

Examiner

Larry R. Helms

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-22,34-44,53 and 54 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3-22, 34-44, 53-54 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

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### DETAILED ACTION

1. Claims 1, 3-22, 34-44 and 53-54 are pending and under examination.
2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

### *Oath/Declaration*

3. The Examiner acknowledges that a new oath is being executed, however, he oath or declaration is still defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is still defective because:

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment [emphasis added] specifically referred to in the oath or declaration.

### *Response to Arguments*

4. The rejection of claims 3-13, 16-22, 34-44, and 53-54, under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 9/21/01 has been carefully considered but has been deemed to be not persuasive. The response states that "Applicants claims only literally read on antibodies that specifically bind to the c-erbB2 receptor as indicated" (see page 3 of response). In response to this argument, the claims are directed to antibodies

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that bind to the same epitope as bound by F5 (SEQ ID NO:1 or C1 (SEQ ID NO:2), not just those that bind to the c-erbB2 receptor. As stated in a previous Office Action as evidenced by Greenspan et al and Knight determination of an epitope that an antibody binds to is not predictable. The specification has not taught what epitope the antibodies F5 or C1 bind to. The specification has not taught how to make the invention without undue experimentation. The response further states arguments directed at a utility rejection. In response to these arguments, the rejection was not based on utility.

5. The rejection of Claims 1, 14, 15, 34-38, and 53-54 under 35 U.S.C. 103(a) as being unpatentable over Maier et al (Cancer Res. 51:5361-5369, 1991) and further in view of Bird et al (Science 242:423-426, 1988) is maintained.

The response filed 9/21/01 has been carefully considered but is deemed not to be persuasive. The response states "the Examiner has failed to show how the cited references provide any specific information about the **particular claimed** antibodies" (see page 6 of response) and "There is no teaching or suggestion found in Maier et al or Bird et al that would necessarily lead one skill to an **"antibody specifically binds to an epitope bound by F5 (SEQ ID NO:1) or C1 (SEQ ID NO:2)"** or to an **internalizing antibody.**" In response to these arguments, the burden was properly shifted to Applicants to show an unobvious distinction between the structural and functional characteristics of the claimed antibody and the antibody of the prior art, however, this distinction was not made in the response. In addition, the response states that "While there may have been a general motivation to prepare a single chain anti-ErbB2 antibody" (see page 6 of response). Thus, the response states that there would have been motivation to make the claimed antibody. Therefore, as previously stated the antibody of Maier et al is internalizing and binds to the c-erbB2 receptor and as stated

previously, it appears that Maier et al have produced an antibody that is identical to the claimed antibodies (See In re Best). In addition, as stated in the Office Action of 7/10/01 Bird et al teaches the advantage of single chain antibodies because of their small size (see page 426) for therapy. Thus, it would have been obvious to produce a single chain antibody from the antibody of Maier et al which is directed at the therapeutic target c-erbB2 because of the advantages of the small size and advantages in imaging and therapy in cancer as taught by Bird et al (see page 426 in Bird).

6. Applicant's request for an interview is acknowledged and will be granted upon request

Although applicant has requested this interview prior to this Office Action; this Office Action has been set forth in view of administrative procedures and time constraints.

The examiner apologizes for any inconvenience to applicant in this matter.

#### ***Summary***

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Respectfully,

Larry R. Helms Ph.D.

  
SHEELA HUFF  
PRIMARY EXAMINER